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PATENT
Customer No. 22,852
New Attorney Docket No. 09065.0006-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Robert Frederick VEASEY et al.	)	Group Art Unit: 3767
	)	
Application No.: 10/790,025	)	
	)	Examiner: Shefali Dilip PATEL
Filed: March 2, 2004	)	
	)	
For: PEN-TYPE INJECTOR	)	Confirmation No. 9747

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests a pre-appeal brief review of the rejections applied against this application in the Final Office Action mailed April 30, 2009. This Request is being filed concurrently with a Notice of Appeal, a petition for one-month extension of time, and extension fee.

I. Compliance With Requirements For Submitting a Pre-Appeal Brief Request for Review

This submission complies with the requirements for requesting a pre-appeal brief review because: (i) the present application has been at least twice rejected; (ii) this Request is being filed concurrently with a Notice of Appeal and (iii) prior to the filing of an Appeal Brief; and (iv) this Request is five (5) or less pages in length and sets forth legal and/or factual deficiencies in the outstanding final rejections. *See* Official Gazette Notice, July 12, 2005.

II. Status of the Claims

Claims 1-18 and 22 are pending, of which claims 1, 2, and 22 are independent. Claims 5, 6, 9, 10, and 16 were previously withdrawn. In the Final Office Action mailed April 30, 2009 ("the Final Office Action"), claims 1-4, 7, 8, 11-15, 17, 18, and 22 were rejected under 35

U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0052578 to Moller ("Moller").

III. Grounds for Traversing the Rejections

A. The Rejection of Claims 1-4, 7, 8, 11-15, 17, 18, and 22 is Legally Deficient Because Moller Does Not Anticipate these Claims

In order to properly establish that Moller anticipates Applicant's claims under 35 U.S.C. § 102, each and every element as set for the in the claims must be found, either expressly or inherently described, in a single prior art reference. M.P.E.P. § 2131., 8th Ed., Rev. 7 (July, 2008). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Id.* (quoting *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236 (Fed. Cir. 1989)).

With regard to claim 1, Moller fails to disclose or suggest, among other things, a "unitary housing" and a "cartridge . . . enclosed within the housing together with [a] dose selecting means and [a] dose expelling means," as recited in claim 1. The Examiner asserts that Moller discloses, *inter alia*, a dose selecting means (dose setting drum 17 or 117) and a dose expelling means (tubular element 20 or 120) and a unitary housing 1 or 101 with which the dose selecting means and the dose expelling means are retained. Final Office Action, pp. 4-5. Moller, however, does not disclose a "cartridge . . . enclosed within the housing together with [a] dose selecting means and [a] dose expelling means." Instead, Moller discloses a cartridge that is detachable from the housing, and not contained within the housing as claimed. For example, as shown in the left-hand figure on sheet 3 (figure not numbered), Moller depicts a threaded part of a compartment 103 through which a cartridge (not shown) is coupled to the compartment 103. This cartridge is not enclosed within the housing with the tubular element 120 and the dose setting drum 117.

In the Final Office Action, the Examiner stated that "since the compartment [3] is a section of the housing [1], at least a portion of the cartridge ("ampoule") will be contained within the housing when the cartridge is inserted into the compartment [3] (Figure 1)." Final Office Action, p. 3. This argument is flawed. Claim 1 does not merely require the cartridge to be "retained" within the housing as the Examiner improperly asserts, but rather, requires that "the cartridge is enclosed within the housing together with the dose selecting means and the dose expelling means."(Emphasis added.) Those of ordinary skill in the art would immediately appreciate that to be "enclosed" requires more than to be "retained." The ordinary meaning of

the word "enclose" is "[t]o surround on all sides, close in." (The American Heritage College Dictionary, page 461, 4th ed. 2004.) In contrast, at best, the device of Moller, as characterized by the Examiner, merely borders a portion of the cartridge ("ampule"). Therefore, it is clear that the housing 1 or 101 of Moller fails enclose a cartridge, the dose selecting means, and the dose expelling means together.

Accordingly, Applicant submits that the Moller fails to disclose or suggest the above-discussed feature of claim 1. For at least the above reason, Applicant submits that independent claim 1 is allowable over Moller. Accordingly, Applicant requests the allowance of independent claim 1.

With regard to claim 2, Moller fails to disclose, among other things, "ratchet means associated with the insert to ensure the piston rod only rotates in a single direction through the insert," as recited in claim 2. Fig. 1 of Moller illustrates a system that includes nut 13 on the piston rod 32 engaged with the insert. The Examiner asserts that the nut 13 of Moller corresponds to ratchet means of the present application. Final Office Action, page 5. However, in the discussion of the nut 13 of Fig. 1 of Moller, the following comments are made:

> To set a dose the dose setting button 18 is rotated to screw the dose setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and be lifted with this drum up from the end of the housing 1. . . . The rotation of the dose setting button 18 and the cup shaped element is further transmitted to the gearbox 9 through the protrusions 23 on this gearbox engaging the longitudinal recesses 22 in the inner wall of the tubular part 20 of said cup shape element. The rotation of the gearbox 25 is through the connection bars 12 transmitted to the nut 13, which in this way is screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose is set. . . . To inject a set dose the injection button is pressed . . . Through the gear box 9 the force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2.

(Moller, pp. 2-3, paragraphs [0029-0032]). Moller further states "[a] too high set dose can be reduced by rotating the dose-setting button 18 *in the opposite direction* of the direction for increasing the dose." (Moller, p. 2, paragraph 29, emphasis added.) In summary, nut 13 is connected to gear box 9 via rods 12, which is further connected to the cup-shaped element, which is in turn connected to dose-setting button 18. Since the button 18 is rotatable in both

directions, it follows that the nut is likewise rotatable in both directions. Therefore, the piston rod which is connected to the nut is also rotatable in both directions.

Claim 2 requires that the "ratchet means associated with the insert...ensure[s] [that] the piston rod only rotates in a single direction through the insert." Moller discloses that the nut 13 can move up and down along the thread of the piston rod 4 and thus allows the bidirectional rotation of the piston rod 4 relative to the nut 13. At least for this reason, Applicant submits that Moller does not disclose or suggest all of the features of claim 2 and thus cannot anticipate claim 2.

Furthermore, a nut cannot constitute a ratchet at least because the Examiner has not shown that the cited nut has a ratcheting ability and because nuts are not conventionally known in the art to include ratcheting means.

For at least the above reasons, Applicant submits that independent claim 2 is allowable over Moller. Accordingly, Applicant requests the allowance of independent claim 2, and for at least the same reasons, the allowance of claims 3, 4, 7-9, 11-15, 17 that depend from claim 2. Further, upon allowance of claim 2, Applicant respectfully requests rejoinder and reconsideration of non-elected claims 5, 6, 10, and 16, which depend from claim 2.

With regard to claim 22, Moller fails to disclose, among other things, "a dose expelling means that directly engages an end of [a] piston rod." The Examiner asserts that Moller discloses a "dose expelling means [20][13] [which] directly engages an end of the piston rod[4]." Final Office Action, p. 8. Moller, however, does not disclose such a feature. Instead, Moller discloses, at best, a dose expelling means that contacts a *side* of the piston rod as clearly shown in Figure 1.

For at least the above reason, Applicant submits that claim 22 is allowable over Moller. Accordingly, Applicant requests the allowance of claim 22.

III. Grounds for Traversing the Withdrawal of Claim 9

With regard to dependent claim 9, in its Response to the Restriction/Election Requirement of November 30, 2007, Applicant submitted that claims 5, 6, 10, and 16 are drawn to a non-elected species. However, claim 9 was not in the listing of withdrawn claims and Applicant traverses the withdrawal of claim 9 for at least the following reason. The Examiner maintains "there is no specific recitation of the limitation 'rigid keying' in the Specification in

relation to Figures 1-5." Final Office Action, page 2. However, the feature, "rigid keying of the portions of the dose dial sleeve together" depicted in Fig. 6 of non-elected Species II is the same as the engaging feature between portions of dose dial sleeve depicted in Figs. 1-5 and thus reads on Figs. 1-5. Further, "[t]here is *no requirement that the words in the claim must match those used in the specification disclosure*. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision." *See M.P.E.P. § 2173.05(e), 8th Ed., Rev. 7 (July. 2008).* (Emphasis added.) Therefore, the Applicant respectfully submits that claim 9 reads on elected Species I and should be considered on its merits with elected claims 1-4, 7, 8, 11-15, 17 and 18.

IV. Conclusion

In light of the above arguments, the rejections of the claims are each legally deficient. Because the Examiner's rejections of the claims, as set forth in the Final Office Action and maintained by the Advisory Action, include legal deficiencies, Applicant is entitled to a pre-appeal brief review of the Office Action. Based on the foregoing arguments, Applicant requests that the rejection of these claims be withdrawn and the claims allowed.

Respectfully submitted,
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Dated: August 31, 2009

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